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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE, INCORPORATED,

Plaintiff,

v.

VYSIS, INC.,

Defendant.

CASE NO. 99CV 2668H (AJB)

VYSIS' OPPOSITION TO GEN-PROBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Date: June 8, 2001
Time: 10:30 a.m.
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I. INTRODUCTION

The circumstances leading to commencement of this suit by Gen-Probe Incorporated ("Gen-Probe") require close scrutiny of its myriad allegations that the patent in suit, owned by Vysis Inc. ("Vysis"), is invalid and not infringed. Having failed to appreciate the value of the present invention until **after** Vysis suggested its value to Gen-Probe in 1994, having thereafter adopted the patented technology as solving the problems that Gen-Probe itself concedes had been the "Achilles' heel" of earlier assay products, having insisted that it be granted a license under the Vysis patent as a condition to settlement of prior unrelated litigation between the parties, and having to this day scrupulously preserved for itself the protections provided by the license, Gen-Probe now comes before this Court seeking to avoid its obligations to pay royalties under that license agreement. Gen-Probe does so by presenting a series of factual and legal contentions that are irreconcilable with its own conduct, the clear prosecution history of the patent in suit, and well settled patent law.

The allegations upon which Gen-Probe's present motion for summary judgment is based cannot withstand close scrutiny. Gen-Probe asks this Court to read into the Vysis patent claims a requirement for non-specific amplification. Yet, when the available intrinsic evidence that must be considered in all matters of claim construction – the claims, the patent specification, and the prosecution history – point unambiguously in the other direction. The text of the patent makes specific reference to "specially tailored primers" of the sort used in specific amplification processes, the patent owner stated repeatedly during prosecution leading to issuance of the patent that "[t]argets can be amplified by a number of ways including PCR," which is perhaps the most notorious specific amplification technique of all, and the U.S. Patent and Trademark Office (PTO) specifically stated in its reasons for allowance of the patent that it related to "PCR amplification." A fatal flaw in Gen-Probe's motion is the complete failure even to address the prosecution history of the patent. Much of the material offered by Gen-Probe in support of its position falls instead into the category of "extrinsic" evidence, including alleged evidence of the inventors' subjective intent, which the Federal Circuit has repeatedly indicated should not be considered on the issue of claim construction. Under these circumstances, Gen-Probe's suggestion that the patent claims should be read in a way

that would exclude specific amplification techniques, such as PCR, borders on the frivolous and must be rejected as a matter of law.

II. THE CLAIMS OF THE '338 PATENT ARE NOT LIMITED TO NON-SPECIFIC AMPLIFICATION

A. Claim Construction Requires Review of the Prosecution History of the Patent

In its effort to ignore the prosecution history of the patent in suit -- U.S. Patent No. 5,750,338 ("the '338 patent") -- Gen-Probe badly misstates the law applicable to claim construction. Citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), Gen-Probe makes the following statement in its memorandum:

> In determining the proper construction of a claim, the Court has numerous sources that it may properly utilize for guidance. Cite omitted. These sources include both "intrinsic" evidence (e.g., the patent specification) and "extrinsic" evidence (e.g., expert testimony and the inventor's/patent owner's own descriptions of the invention).

Gen-Probe Memorandum ("Memo.") at 8.

Gen-Probe's statement of the applicable law is a gross mischaracterization of what the *Vitronics* court actually said. The court said:

> In determining the proper construction of a claim, the court has numerous sources that it may properly utilize for guidance. These sources . . . include both intrinsic evidence (e.g., the patent specification **and file history**) and extrinsic evidence (e.g., expert testimony).

Id. (emphasis added). The *Vitronics* court went on to state that the prosecution (or file) history "is often of **critical significance** in determining the meaning of the claims." *Id.* (emphasis added). Indeed, the *Vitronics* court concluded that "it is **improper** to rely on extrinsic evidence" when "the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Id.* at 1583 (emphasis added).[1]

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[1] In a further attempt to obscure the importance of the prosecution history to claim construction, Gen-Probe, at page 13 of its Memo, also crops a quote from *Wright Medical Technology, Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997). Gen-Probe quotes from the case: "The proper construction of the claims is based upon the claim language, the written description portion of the specification including any relevant drawings . . ." but omits the court's reference to the "prosecution history."

The Federal Circuit's seminal claim construction case of *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996), held that a patent's prosecution history "is of **primary significance** in understanding the claims." (Emphasis added.) Indeed, the Federal Circuit has stated that the failure to consider the prosecution history during claim construction is error. *Lemelson v. United States*, 752 F.2d 1538, 1550 (Fed. Cir. 1985).

This Court, citing *Markman*, has recognized that courts **must** consider the prosecution history, if in evidence, when construing patent claims, along with the claims themselves and the specification. *Lee's Aquarium & Pet Products, Inc. v. Python Pet Products, Inc.*, 951 F. Supp. 1469, 1472 (S.D. Cal. 1997), *aff'd*, 152 F.3d 945 (Fed. Cir. 1998). In that case, this Court also agreed with *Vitronics* that it is improper for the court to rely on extrinsic evidence if an analysis of the intrinsic evidence (claim language, specification, and prosecution history) resolves any ambiguity. *Id.*

The Federal Circuit in *Markman* eloquently explained why the type of evidence offered by Gen-Probe has little or no weight in determining the scope of a claim and why the prosecution history of a patent is intrinsic evidence that must be considered in claim construction:

> No inquiry as to the subjective intent of the applicant or PTO is appropriate or even possible in the context of a patent infringement suit. The **subjective intent of the inventor** when he used a particular term **is of little or no probative weight** in determining the scope of a claim (**except as documented in the prosecution history**). . . . While presumably the inventor has approved any changes to the claim scope that have occurred via amendment during the prosecution process, **it is not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO**. [Citation omitted.] Of course the views of the other party to the "patent contract," the government, are generally not obtainable, **except as reflected in the prosecution history**. . . .
>
> Moreover, ideally there should be no "ambiguity" in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history. . . . Patent applications, unlike contracts, are reviewed by patent examiners, quasi-judicial officials trained in the law and presumed to "have some expertise in interpreting the [prior art] references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents." [Citations omitted.] **If the patent's claims are sufficiently unambiguous for the PTO, there should exist no factual ambiguity when those same claims are later construed by a court of law in an infringement action**.

Markman, 52 F.3d at 985-86 (emphasis added).

Gen-Probe completely ignores the clear pronouncements in these binding precedents that the prosecution history is intrinsic evidence that must be considered in determining the meaning of a patent claim and instead relies heavily on the inventor's/patent owner's recollections of the invention that the courts have held are extrinsic evidence not normally considered in claim construction. Why Gen-Probe did this is clear. An examination of the prosecution history of the '338 patent unambiguously establishes that the PTO and the patent owner both believed that specific amplification was included in the invention claimed by the '338 patent, which is fatal to Gen-Probe's motion.

B. The Prosecution History Belies Gen-Probe's Asserted Claim Construction

The claims of the '338 patent are directed to methods or kits for amplifying or detecting a target polynucleotide in a sample by combining the techniques of target capture with amplification. As Gen-Probe correctly points out in its memorandum, the claims include the step of "amplifying" the target polynucleotide. Gen-Probe argues that the proper meaning of the term "amplifying" in the claims is limited to non-specific amplification. The prosecution history of the '338 patent, however, unambiguously belies Gen-Probe's contention.

The prosecution history of the '338 patent, the history of the correspondence between the patent owner and the PTO, leads to the inescapable conclusion that both the patent owner and the PTO (no fewer than five different Patent Office Examiners) considered the claimed invention to encompass the polymerase chain reaction ("PCR"), which is a type of specific amplification.[2]

The initial application for the '338 patent included a broad claim (claim 1), which recited the step of "subjecting said removal product to amplification . . . ." Exhibit ("Ex.") A to Declaration of Thomas W. Banks in Support of Vysis' Opposition to Gen-Probe's Motion for Partial Summary Judgment ("Banks Decl."), p. 61.[3] In rejecting the claims of the original '338 patent application in

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[2] The following discussion of the prosecution history is based primarily on the Declaration of David H. Persing In Support Of Vysis' Opposition To Gen-Probe's Motion For Partial Summary Judgment ("Persing Decl.").

[3] It is noteworthy in this regard that original dependent claim 11 contained language specifically further limiting the claim to "non-specific" amplification, which language was never incorporated into the broad claims. Banks Decl., Ex. A. The patent owner clearly knew how to exclude the disclosed use of specific amplification had it wanted to, but did not.

the PTO's first Official Action, Patent Examiner Scott A. Chambers, Ph.D, and Primary Patent Examiner Amelia Burgess Yarbrough cited as prior art the basic Mullis PCR patents. Banks Decl., Ex. B, pp. 3-4. Clearly, if the Patent Examiners had believed that the claims of the '338 patent application were limited to non-specific amplification, it would have been illogical for them to have cited the PCR patents against the application, because PCR is a type of specific amplification. Thereafter, Examiner Chambers and Primary Examiner Margaret Moskowitz continued to cite the Mullis PCR patents against the pending patent claims. Banks Decl., Ex. C, p.3, and Ex. D, p.3.

In responding to rejections of the pending claims based on the Mullis PCR patents, the owner of the '338 patent never attempted to distinguish the Mullis patents by arguing that Mullis disclosed specific amplification, whereas the invention of the '338 patent was directed to non-specific amplification. To the contrary, the patent owner repeatedly emphasized that the invention included PCR-type amplification:

> Applicant's invention principally serves to enhance the sensitivity of nucleic acid hybridization assays utilizing target amplification. **Targets can be amplified by a number of ways including PCR**. Applicant's invention enhances sensitivity by eliminating from the amplification medium extraneous (nonspecific) nucleic acids which might otherwise be amplified by PCR thereby introducing noise into the assay.

Banks Decl., Ex. E, p.18 (responding to November 5, 1992 Office Action in application serial no. 07/944,505) (emphasis added).

If the patent owner had considered the invention to be limited to non-specific types of amplification, it undoubtedly would have argued this to the PTO to overcome the rejection of the patent claims based on the Mullis PCR patents, which disclosed specific amplification. Instead, the patent owner maintained all along that the invention encompassed PCR and argued that the invention was not obvious in view of the PCR patents. Persing Decl., ¶ 16.

The official recognition that the '338 patent claims encompassed specific amplification techniques like PCR persisted through the very end of the patent procurement process. Indeed, Patent Examiner Dianne Rees, Ph.D., and Primary Patent Examiner W. Gary Jones make it clear in the very first sentence of their Examiner's Statement of Reasons for Allowance that they considered the claims of the '338 patent to encompass specific amplification techniques such as PCR:

> The claims are drawn to methods of **PCR amplification** wherein the target is first separated from the sample by using a support that binds to the target polynucleotide and then amplified.

Banks Decl., Ex. F, p.2 (emphasis added).

The only reasonable conclusion to be reached upon reading the prosecution history of the '338 patent is that both the patent owner and the five patent examiners who examined the patent application believed that the term "amplify" in the patent claims included specific amplification. Persing Decl., ¶ 18.

If the PTO's views from the original prosecution history were not enough, the PTO has adhered to these views in reissue proceedings. In its Protest to Vysis' reissue application for the '338 patent, Gen-Probe presented to the PTO the argument set forth in this motion that the specification of the '338 patent does not provide a basis for claiming specific amplification after target capture. The PTO has indicated that it disagrees with Gen-Probe's interpretation of the '338 patent, stating in a January 16, 2001 Interview Summary that "the specification [of the '338 patent] provided basis for both specific and non-specific amplification of targets subsequent to capture." Banks Decl., Ex. G, pp. 3-4.

The Federal Circuit has made it clear that the Patent Examiner's understanding of the meaning of patent claims developed during prosecution is relevant to construing the proper scope and meaning of those terms. *Markman*, 52 F.3d. at 983 ("It is evident from Markman's explanation of the claims to the examiner that he used 'inventory' in the patent and the examiner understood 'inventory' to consist of 'articles of clothing.'"); *Toro Co. v. White Consolidated Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999) ("Determining the limits of a patent claim requires understanding its terms in the context in which they were used by the inventor, considered by the examiner, and understood in the field of the invention.").

Federal District Courts, including this Court, have followed the Federal Circuit's direction and relied on the meaning of claim terms adopted by the PTO during patent prosecution in construing the meaning of patent claims. *Synthes v. Depuy Ace Medical Co.*, 1999 U.S. Dist. LEXIS 18173, *12-16 (E.D. Pa. 1999) (court declined to construe patent claim terms narrowly because Patent Examiner had rejected the claims based on prior art that met those terms only if construed

broadly); *Sport Squeeze, Inc. v. Pro-Innovative Concepts, Inc.*, 51 U.S.P.Q.2d 1764, 1769 (S.D. Cal. 1999) ("the prosecution history of all three patents reveals that both [the inventor] and the patent examiner understood that differing particle sizes were significant in light of [the prior art]").

Here, the case is even stronger than in *Synthes* for refusing the proferred narrow construction of the disputed claim language. The Patent Examiners of the '338 patent application rejected the claims in view of prior art disclosing the very embodiment, specific amplification, that Gen-Probe contends should not be included within the term "amplify." The patent owner, in response, explicitly acknowledged that the claims encompassed specific amplification techniques, such as PCR. Moreover, in the **very Reasons for Allowance** of the claims of the '338 patent, the PTO Examiners clearly stated their position that the claims included specific amplification, such as PCR.

The prosecution history of the '338 patent makes it clear that not only the patent owner but also the PTO considered specific amplification as included within the claimed term "amplify." As the Federal Circuit observed in *Markman*, "[i]f the patent's claims are sufficiently unambiguous for the PTO, there should exist no factual ambiguity when those same claims are later construed by a court of law in an infringement action." *Markman*, 52 F.3d at 986.

C. The Specification of the '338 Patent Does Not Limit the Claims to Methods Using Non-Specific Amplification

The reason for this unambiguous construction of the patent claims during prosecution as encompassing specific amplification becomes clear from a review of the patent specification. As pointed out in detail below, the specification of the '338 patent describes as one of the particular benefits of the invention that it **permits** the use of non-specific amplification. Gen-Probe, however, points to nothing in the '338 specification that in any way states that non-specific amplification **is** the invention or **must** be used.

1. The '338 Patent Specification

The primary discussion of the invention of combining target capture with amplification begins at column 30, line 15 of the '338 patent specification.[4] The invention is first defined broadly by the statement that "[t]he sensitivity of the above DNA or RNA target capture methods can be enhanced by **amplifying** the captured nucleic acids." (Emphasis added.) The specification then describes a particular benefit of the invention, that "[t]his **can be** achieved by non-specific replication using standard enzymes . . . ." (Emphasis added.) The specification does **not** say that enhanced sensitivity of the target capture methods **is** achieved by non-specific amplification, but rather uses **permissive** language, i.e., that enhanced sensitivity **can be** achieved by non-specific amplification.

The specification then again describes the invention as including amplification generally in the paragraph at column 30, lines 23-29. The paragraph following this describes both specific and non-specific amplification, but points out the particular benefits of the invention when using non-specific amplification:

> Amplification of the target nucleic acid sequences, because it follows purification of the target sequences, **can** employ non-specific enzymes or printers (i.e. enzymes or primers which are capable of causing the replication of virtually any nucleic acid sequence). Although any background, non-target, nucleic acids are replicated along with target, this is not a problem because most of the background nucleic acids have been removed in the course of the capture process. Thus **no specially tailored primers are *needed*** for each test, and the same standard amplification reagents can be used, regardless of the targets.

Col. 30, lines 30-40 (emphasis added).

The reference to "specially tailored primers" is an explicit reference to specific amplification techniques. The specification does not say that such specific techniques cannot be used. Rather, the '338 specification simply shows that the use of target capture in accordance with the invention **makes it possible** to use non-specific primers (i.e., non-specific amplification). Without target capture prior to amplification, non-specific amplification would not be a viable technique for

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[4] The following description of the specification of the '338 patent is based on the Persing Declaration.

detecting target nucleic acids in a sample because non-specific amplification causes the replication of virtually any nucleic acid sequence. However, this is not a problem because the invention of the '338 patent provides a target capture step that removes background, non-target nucleic acids from the sample prior to amplification. The specification does not state that one would not want to use specially tailored primers, but only that such primers are **not needed** in this invention. Thus, the specification simply discloses an important advantage of the invention, that is, because of the preceding target capture step, either specific or non-specific amplification can be successfully used in nucleic acid detection assays; whereas without the invention, only specific amplification could be used. Persing Decl., ¶ 11.

The disclosure at column 30, lines 15-40 of the '338 patent specification tells those of ordinary skill in the art that, while the use of target capture made it possible to use non-specific amplification in assays for detecting nucleic acids, the invention was more generally directed to the use of target capture prior to either specific or non-specific amplification. The benefits of the invention, i.e., purifying the sample by removing non-target materials such as contaminants and inhibitors that can interfere with the amplification step, would also be obtained with specific amplification. If the inventors had wanted to limit the invention to non-specific amplification, it is difficult to imagine that they would have drafted the specification as they did. Persing Decl., ¶ 12.

Gen-Probe acknowledges, as it must, the **permissive** rather than **mandatory** disclosure of the '338 patent specification regarding non-specific amplification:

> The inventors . . . pointed out that one of the express benefits of their invention was that it **permitted** the use of non-specific enzymes and non-specific primers.

Memo, p. 11.

Gen-Probe argues that the examples of the '338 patent disclose only non-specific amplification and relies on the declaration of Dr. Joseph Falkinham, wherein he stated that "the primers described in the ['338] patent are not pre-selected to bind to specific nucleotide sequences as part of the amplification process" and that Example 5 describes only non-specific amplification. Memo, pp. 11-12, and Falkinham Declaration ("Decl."), ¶¶ 14 and 31.

Contrary to Gen-Probe's contentions, however, Example 5 of the '338 patent **does** disclose the use of a specific primer. In particular, while Example 5 states initially that random oligohexamer primers can be used to achieve non-specific amplification, Example 5 also discloses that "[a]lternatively, the double stranded DNA can be formed by synthesis starting from capture probe a." Col. 31, lines 48-49. In this instance, the capture probe acts as the primer. Since the capture probe binds specifically to the target DNA, the capture probe would be a specific primer to the target. This is an example of specific amplification because the primer, capture probe a, binds to a specific, unique DNA sequence in the target organism. Persing Decl., ¶ 13.

The **most** that can be said of the specification of the '338 patent in support of Gen-Probe's position is that it describes specific amplification as not being the preferred embodiment of the invention. It is well settled, however, that patent claims should not be read as excluding disclosed but not preferred embodiments of the invention. *Tate Access Floors, Inc. v. Maxcess Technologies, Inc.*, 222 F.3d 958, 966 (Fed. Cir. 2000)

2. Gen-Probe's Cited Authority Relates to Descriptions of The Invention Using Mandatory Rather Than Permissive Language

The cases relied on by Gen-Probe in support of its argument are easily distinguishable in that each involved a patent specification that described a particular embodiment not as a preferred embodiment, but as the invention itself. In *Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377 (Fed. Cir. 1999), the patent specification always described the disputed term "frame" as being specific to "characters." Thus, the court concluded that the term included "character-based systems" but not "bit-mapped display systems." *Wang* at 1381. In contrast to *Wang*, the '338 patent specification clearly describes the embodiment of non-specific amplification in permissive and not mandatory language. Moreover, in *Wang*, unlike here, the only mention in the specification of the alternative embodiment ("bit-mapped display systems") was in the Background of the Invention, which the court viewed as simply an acknowledgement of the state of the art and not an enlargement of the invention. *Wang* at 1382. In contrast, here specific amplification is described in the patent examples.

Finally, the prosecution history in *Wang* supported the limitation to character-based frames. During prosecution the patent applicant had distinguished prior art on the basis that it "encodes pictorial information . . . on the pel [picture element] level, rather than on the character level." *Wang* at 1384. Here, in contrast, the prosecution history makes it clear that the Patent Office (five different Patent Examiners) and the patent owner all considered the embodiment that Gen-Probe argues should be excluded from the claim, specific amplification, to be within the scope of the claimed invention.

In *Scimed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001), also relied on by Gen-Probe, the patent specification unequivocally described the embodiment of a **coaxial** lumen structure as the "basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." *Scimed* at 1339. The court added that "from the outset the specification identifies the inflation lumen, as that term is used in the Scimed patents, as annular, i.e., **coaxial** rather than **dual** in structure." *Scimed* at 1342 (emphasis added). Accordingly, the court limited the scope of the asserted claims to catheters with **coaxial** lumens and held that the patent disclaimed **dual** lumens. *Scimed* at 1340. In contrast to the '338 specification, the specification in *Scimed* used mandatory rather than permissive language making it clear that the invention **was** the use of coaxial lumens, not dual lumens. Also, unlike the present case, the specification in *Scimed* distinguished the invention from prior art that disclosed dual lumens and pointed out the advantages of coaxial lumens. *Scimed* at 1342-43. Finally, unlike here, the court noted that there was nothing pertinent to the issue of claim construction in the prosecution history. *Scimed* at 1340.

In *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576 (Fed. Cir. 1997), also relied on by Gen-Probe, the issue was the proper meaning of the claim term "passage." All of the "passage" structures contemplated by the specification were either non-smooth or conical. In addition, the specification distinguished the invention from prior art geometries by stating:

> A number of **different geometries** for the second section **are contemplated**, including those having an **irregular shaped** surface or **noncylindrical** shape. **In contrast**, the **prior art** has generally specified that the pneumatic tubing and passageways between the trap and GC are **smooth-walled**.

O.I. Corp. at 1581 (emphasis added). Thus, *O.I. Corp.* is easily distinguishable from this case. Here, the specification of the '338 patent did not distinguish the invention from prior art disclosing specific amplification.[5] The *O.I. Corp.* court also noted that there was nothing identified in the prosecution history contrary to these limiting statements. Based on the specification, the court held that the term "passage" did not encompass a smooth-walled, completely cylindrical structure. *O.I. Corp.* at 1581.

Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362 (Fed. Cir. 2000), also relied on by Gen-Probe, is also readily distinguishable from this case. In that case, the court relied on the unequivocal statement in the patent specification that "any of the back panels would be constructed of a relatively stiff material" in holding that the claimed "back panel" needed to be "relatively stiff." *Kraft* at 1367. The language in the specification in *Kraft* was mandatory, rather than permissive as in this case. Moreover, in *Kraft*, the prosecution history supported the narrow claim construction because the examiner acknowledged during prosecution that the specification provided a description of the back panel material as being stiff. *Kraft* at 1369.

Because the specification of the '338 patent describes non-specific amplification with permissive rather than mandatory language and also describes the use of specific amplification, the '338 patent specification differs significantly from the specifications in the cases relied on by Gen-Probe, which described a particular embodiment as **being** the invention. The specification of the '338 patent simply points out the benefits of the invention in **permitting** the use of non-specific amplification. It does not limit the invention to non-specific amplification and does not exclude specific amplification. Those skilled in the art reading the '338 patent specification would understand that the invention includes specific amplification. Persing Decl., ¶¶ 7, 19.

[5] In fact, when faced with rejections based on prior art disclosing PCR, a type of specific amplification, the owner of the '338 patent declined to limit the invention to exclude specific amplification and instead acknowledged that the invention included PCR.

D. Gen-Probe's Extrinsic Evidence Should Be Given No Weight

1. The Falkinham Declaration Should Be Given No Weight Because He Did Not Consider The Prosecution History

Gen-Probe relies on a declaration by Joseph Falkinham stating his opinion that one of ordinary skill in the art would have understood the term "amplifying" as used in the claims of the '338 patent to mean amplifying by use of non-specific amplification, and would not have understood the term "amplifying" to mean amplifying by use of sequence-specific amplification methods. Falkinham Decl., ¶¶ 5, 52. Dr. Falkinham's declaration should be given little, if any, weight, however, because it is based only on a review of the specification and claims of the '338 patent, and did not consider the prosecution history of the '338 patent. Falkinham Decl., ¶ 4. Moreover, the Falkinham declaration is based on a factually incorrect allegation that use of specific primers is not disclosed in the '338 patent. Persing Decl., ¶ 13.

In contrast, Vysis submits herewith the declaration of its expert, Dr. David H. Persing, based on a full consideration of all of the intrinsic evidence, which the Federal Circuit has stated will in most instances alone resolve any ambiguity in a disputed claim term. *Vitronics*, 90 F.3d at 1583. Dr. Persing, after considering the claims, specification, and pertinent prosecution history of the '338 patent, disagrees with Dr. Falkinham and states that, in his opinion, the '338 patent claims include specific types of amplification. Persing Decl. ¶¶ 4, 6, 7, 19. Dr. Persing bases that opinion on (a) his belief that those of ordinary skill in the art as of December 21, 1987 reading the specification of the '338 patent would conclude that the term "amplify" as used in the claims of the '338 patent includes specific amplification, and (b) his review of the prosecution history of the '338 patent showing that both the patent owner and the patent examiners considered the invention to encompass specific amplification techniques such as PCR. Persing Decl. ¶¶ 8-18.

2. The Testimony Of The Patent Owner's Ex-Employees Should Be Given No Weight

Gen-Probe relies heavily on testimony of two former employees of Vysis' predecessor company Gene-Trak Systems -- Jon Lawrie, one of the inventors of the '338 patent, and Jim Richards, a business development person. According to the Federal Circuit, this testimony should be given little, if any, weight:

> [t]he **subjective intent** of the **inventor** when he used a particular term is of **little or no probative weight** in determining the scope of a claim **(except as documented in the prosecution history)**. . . . it is not unusual for there to be a significant difference between what an inventor thinks his patented invention is and what the ultimate scope of the claims is after allowance by the PTO.

Markman, 52 F.3d at 985.

Thus, the testimony of inventor Lawrie is simply irrelevant to the claim construction issue. Moreover, Gen-Probe relies on only some of Dr. Lawrie's testimony while ignoring other testimony. For example, Gen-Probe cites testimony from Dr. Lawrie that the '338 patent was directed to methods separate from PCR, but ignores Dr. Lawrie's testimony that he believed that the invention of the '338 patent "is not limited to nonspecific amplification." Banks Decl., Ex. H, p. 262, lns. 8-14.

Gen-Probe also relies heavily on a document authored by Jim Richards and testimony from Richards about that document purportedly relating to the invention of the '338 patent. This document and the Richards testimony are utterly irrelevant to the claim construction issue. First of all, Jim Richards is not even an inventor of the '338 patent, and in fact worked in business development. Moreover, at his deposition, Richards testified that at the time he authored the document Gen-Probe relies on, he had not even read the patent application that eventually issued as the '338 patent. Banks Decl., Ex. I, p. 184, lns. 7-9.

Accordingly, the testimony of these ex-employees should have no bearing on the proper interpretation of the '338 patent claims.

III. CONCLUSION

For the reasons pointed out herein, Gen-Probe's motion should be denied.

Date: May 25, 2001

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